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IP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/214,453	10/25/99	LEADLAY	P

000110 HM12/0319  
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SUITE 720  
1601 MARKET STREET  
PHILADELPHIA PA 19103-2307

EXAMINER

KERR, K

ART UNIT	PAPER NUMBER
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1652

13

DATE MAILED: 03/19/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/214,453**

Applicant(s)  
**Leadlay et al.**

Examiner  
**Kathleen Kerr**

Group Art Unit  
**1652**



☒ Responsive to communication(s) filed on 10/6/00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-3 and 24-43 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-3 and 24-43 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1652

## **DETAILED ACTION**

### ***Application Status***

1. A preliminary amendment was filed on October 25, 1999 which deleted claims 4-23. A second preliminary amendment was filed on October 25, 1999 which amended claim 1 and added new claims 24-43. Thus, Claims 1-3 and 24-43 are pending in the instant application.

### ***Restriction***

2. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 24-39, drawn to hybrid PKS genes, vectors thereof, transformed organisms thereof, methods of making said transformed organisms, methods of making polyketides using said organisms, and hybrid PKS enzymes.

Group II, claim(s) 40, drawn to polyketides.

Group III, claim(s) 41-43, drawn to type II PKS promoters linked to heterologous genes.

Art Unit: 1652

3. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The special technical feature of the first invention(s), Group I, is a hybrid PKS gene cluster. Said technical feature is a product which is modified in subsequent claims in Group I. Said product is also part of a large vector and/or host cells in Group I. Methods of making a transformed organism are considered the first method of making a product which includes the special technical feature, which methods are included in Group I. Methods of using a transformed organism are considered the first method of using a product which includes the special technical feature, which methods are included in Group I. Moreover, the hybrid PKS enzyme, although it is a distinct product, is directly and inextricably linked to the special technical feature of the gene and, thus, also included in Group I.

The polyketides of Group II, although related to the methods of making polyketides in Group I as product-by-process, are distinct products from both the genes and enzymes in Group I with entirely different chemical structures and modes of functioning. Specifically, the genes and enzymes of Group I are biochemical entities which function to encode genes and catalyze reaction, respectively, while polyketides are chemical compounds used as, for example, antibiotics. Moreover, said polyketides are not inextricably linked to Group I since said polyketides can be made by processes other than the methods in Group I, for example, by total

Art Unit: 1652

chemical synthesis or semi-chemical synthesis using products from non-hybrid PKS (non-Group I) enzymes. Thus, Groups I and II lack a corresponding special technical feature.

Groups I and III do not share a special technical feature because Group I is specifically limited to modular, type I PKS genes while the nucleic acids of Group III are drawn to iterative, type II PKS promoters (not PKS genes even) linked to heterologous genes. Thus, Groups I and III lack a corresponding special technical feature.

#### ***Election***

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***Examiner's Comments***

5. Upon a cursory look at the instant claims, the Examiner noted some confusion in the claimed subject matter. To facilitate compact prosecution, the Examiner will note said claims

Art Unit: 1652

below. These notes are not rejections, but requests for clarification to facilitate the first Office action on the merits which will follow Applicant's election. Clarification is not required, but is suggested.

- a. Claim 24 is confusing as to the subject matter which it encompasses. Does this claim read on hybrid PKS genes which encode loading modules with additional KS domains originating from extender modules wherein the loading module is now KS-AT-ACP? Moreover, loading "modules" are typically referred to as ---domains--- in the art.
- b. Claim 28 is confusing as to the subject matter which it encompasses. Do corresponding domains indicate duplicated gene portions?
- c. Claim 30 is confusing as to the subject matter which it encompasses. Is the hybrid PKS gene now to include a ketide directly? The word "leading" is unclear. In view of the art, this claim is likely drawn to a change in specificity of extender modules, but this is unclear in the claim language.

### *Conclusion*

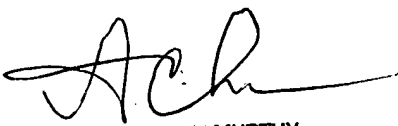
6. Applicants must respond to the instant Office action with an election of the invention to be examined.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Kathleen M. Kerr whose telephone number is (703) 305-1229. The Examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m.

Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
PONNATHAPU ACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

KMK

March 16, 2001